

DAN BURTON, INDIANA
CHAIRMAN

BENJAMIN A. GILMAN, NEW YORK
CONSTANCE A. MORELLA, MARYLAND
CHRISTOPHER SHAYS, CONNECTICUT
ILEANA ROS-LEHTINEN, FLORIDA
JOHN M. MC HUGH, NEW YORK
STEPHEN HORN, CALIFORNIA
JOHN L. MICA, FLORIDA
THOMAS M. DAVIS III, VIRGINIA
DAVID M. MCINTOSH, INDIANA
MARK E. SOUDER, INDIANA
JOE SCARBOROUGH, FLORIDA
STEVEN C. LATOURETTE, OHIO
MARSHALL "MARK" SANFORD, SOUTH CAROLINA
BOB BARR, GEORGIA
DAN MILLER, FLORIDA
ASA HUTCHINSON, ARKANSAS
LEE TERRY, NEBRASKA
JUDY BIGGERT, ILLINOIS
GREG WALDEN, OREGON
DOUG OSE, CALIFORNIA
PAUL RYAN, WISCONSIN
HELEN CHENOWETH, IDAHO
DAVID VITTER, LOUISIANA

ONE HUNDRED SIXTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5074
MINORITY (202) 225-5051
TTY (202) 225-6852

HENRY A. WAXMAN, CALIFORNIA
RANKING MINORITY MEMBER

TOM LANTOS, CALIFORNIA
ROBERT E. WISE, JR., WEST VIRGINIA
MAJOR R. OWENS, NEW YORK
EDOLPHUS TOWNS, NEW YORK
PAUL E. KANJORSKI, PENNSYLVANIA
PATSY T. MINK, HAWAII
CAROLYN B. MALONEY, NEW YORK
ELEANOR HOLMES NORTON,
DISTRICT OF COLUMBIA
CHAKA FATTAH, PENNSYLVANIA
ELIJAH E. CUMMINGS, MARYLAND
DENNIS J. KUCINICH, OHIO
ROD R. BLAGOJEVICH, ILLINOIS
DANNY K. DAVIS, ILLINOIS
JOHN F. TIERNEY, MASSACHUSETTS
JIM TURNER, TEXAS
THOMAS H. ALLEN, MAINE
HAROLD E. FORD, JR., TENNESSEE
JANICE D. SCHAKOWSKY, ILLINOIS

BERNARD SANDERS, VERMONT
INDEPENDENT

March 13, 2000

BY FACSIMILE

The Honorable Jane E. Henney
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Henney:

In concert with Representative Helen Chenoweth-Hage, I am writing to ask questions about the Food and Drug Administration's (FDA) health claims policy for food and dietary supplements and FDA's "Strategy for Implementation of *Pearson* Court Decision" (64 F.R. 67289, Dec. 1, 1999). We are concerned that FDA is continuing to resist implementation of the First Amendment to the United States Constitution and Federal laws that promote public health. By enacting the Nutrition Labeling and Education Act of 1990 (NLEA), the Dietary Supplement Health and Education Act of 1994 (DSHEA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA), Congress directed FDA to encourage expanded consumer access to new nutritional information -- as long as such information is truthful, not misleading, and adequately substantiated.

On January 15, 1999, the United States Court of Appeals for the District of Columbia Circuit for the first time subjected to careful First Amendment examination FDA's interpretation of the "significant scientific agreement" standard governing FDA's health claims approval policy (*Pearson v. Shalala*, 164 F.3d 650 D.C. Cir. 1999). The *Pearson* court applied analysis and standards well established by Supreme Court case law for determining whether FDA regulations that suppress free speech satisfy First Amendment requirements. The court rejected FDA's argument that health claims in labeling present unique issues that require more government regulation than other forms of commercial speech. In fact, the court characterized this line of argument as "almost frivolous" (*Pearson* at 655).

The *Pearson* court held that FDA violated the First Amendment by banning four specific health claims and failing to consider whether those claims could be stated in a nonmisleading manner (*e.g.*, reflecting the weight of the substantiating evidence through the use of qualifying

language). The court further held that FDA violated the Administrative Procedure Act by failing to explain the level of scientific evidence FDA requires under its interpretation of the "significant scientific agreement" standard. The court also noted that, notwithstanding a more complete explanation of FDA's standard, some health claims "with proper disclaimers" might be allowed under the First Amendment even if such claims do not meet the standard (*id.* at 654). The *Pearson* case is final and binding, because FDA did not appeal to the Supreme Court.

Part Six of FDA's December 1, 1999 Strategy announces that FDA will deny all pending and new proposed health claims while FDA develops a comprehensive policy response to the *Pearson* case. Moreover, Part II.A of FDA's January 2000 "Dietary Supplement Strategy (Ten Year Plan)" indicates that developing a comprehensive policy response to the *Pearson* decision is a program goal FDA aims to achieve by the year 2010. This deadline is over 15 years after Congress enacted DSHEA, and 20 years after Congress enacted NLEA. We view delaying implementation for such a lengthy time period as an unwarranted suppression of truthful, First Amendment speech and as a disservice to public health.

Moreover, FDA's implementation strategy makes no commitment to implement the *Pearson* decision with respect to conventional foods, which, like dietary supplements, are subject to the "significant scientific agreement" standard at issue in *Pearson*. Based on these FDA responses to the *Pearson* decision, we are concerned that FDA is continuing to resist Congressional and judicial directives to expand consumer access to truthful, nonmisleading and substantiated health claims.

Therefore, pursuant to the Constitution and Rules X and XI of the United States House of Representatives, we request that you respond to the questions in the enclosure. Please deliver your response to the Subcommittee majority staff in B-377 Rayburn House Office Building and the minority staff in B-350A Rayburn House Office Building not later than noon on Friday, March 31, 2000. If you have any questions about this request, please call Subcommittee Counsel Bill Waller on 226-2067. Thank you for your attention to this request.

Sincerely,



David M. McIntosh

Chairman

Subcommittee on National Economic Growth, Natural
Resources, and Regulatory Affairs

cc: The Honorable Dan Burton
The Honorable Dennis Kucinich
The Honorable Helen Chenoweth-Hage

Enclosure

QUESTIONS REGARDING FIRST AMENDMENT & HEALTH CLAIMS

Q1. The *Pearson* court, following well-established Supreme Court jurisprudence, held that the Food and Drug Administration's (FDA) regulation of health claims is premarket review of commercial speech protected by the First Amendment and, therefore, must be justified by a substantial governmental interest and withstand close scrutiny (*Pearson*, 164 F.3d 650, 655 D.C. Cir. 1999). How does FDA justify its continued suppression of truthful speech that helps consumers make educated decisions to improve their own health? Could FDA avoid violating the First Amendment by approving, as the *Pearson* court suggested, qualifying language or disclaimers that would ensure that the proposed health claims are truthful and not misleading?

Q2. Does the Federal Food, Drug, and Cosmetic Act of 1938, as amended (FD&C Act) (and particularly § 403(r)(5)(D), 21 U.S.C. § 343(r)(5)(D), concerning the standard for approving health claims for dietary supplements), authorize FDA to approve truthful, nonmisleading, and adequately-substantiated health claims that include qualifying language or disclaimers? Is this standard compatible with the First Amendment and the *Pearson* decision? Please provide any evidence in FDA's possession that adoption of such a standard would endanger consumers. Has FDA considered adopting this standard? If not, why not?

Q3. In section 302 of the Food and Drug Administration Modernization Act of 1997 (FDAMA), Congress set deadlines for FDA consideration and completion of rulemakings for health claims for conventional foods (*i.e.*, 100 days for FDA to initiate a rulemaking and 540 days to complete a rulemaking). In 1997, FDA adopted a similar deadline framework for health claims for dietary supplements (21 C.F.R. § 101.70). By what authority can FDA now refuse to comply with these statutory and regulatory deadlines?

Q4. Part II.A of FDA's January 2000 "Dietary Supplement Strategy (Ten Year Plan)" indicates that implementation of the *Pearson* decision is a program goal FDA aims to achieve by the year 2010, which is 16 years after enactment of the Dietary Supplement Health and Education Act of 1994 (DSHEA). Neither FDA's Ten-Year Plan nor FDA's February 10, 2000 "Center for Food Safety and Applied Nutrition [CFSAN] Year 2000 Program Priorities" include any interim implementation deadlines. Please explain why it will take 16 years to implement *Pearson*, when the court held that FDA's health claims policy suppresses free speech protected by the First Amendment? Please provide a timetable that implements the health claims provisions of the Nutrition Labeling and Education Act of 1990 (NLEA), DSHEA, and FDAMA in accordance with the First Amendment and *Pearson* decision, including interim steps and specific deadlines for compliance.

Q5. Section 2.d of FDA's February 2000 CFSAN Year 2000 priorities for dietary supplements states that FDA will "[c]ontinue to review health claim petitions within the statutory timeframe." Does this more recent commitment overrule the denial of all pending health claims FDA announced in its December 1999 "Strategy for Implementation of *Pearson* Court Decision"? If not, please explain what steps FDA will take (including specific deadlines for each step) to resolve this inconsistency and to inform stakeholders and the public about FDA's actual intended practice.

Q6. In contrast to FDA's 1994 policy adopting the same standard for approving health claims for dietary supplements and conventional foods (59 F.R. 395, 405, 422-23, January 4, 1994), FDA's *Pearson* implementation strategy does not address conventional foods. Moreover, in Strategy 2.2 § A.3 of FDA's CFSAN Year 2000 priorities, FDA announced its intention to promulgate this year a final rule amending the health claims regulations governing conventional foods but does not mention the First Amendment or the *Pearson* decision. Please explain the timeframe and specific steps FDA is taking to ensure that this final rule governing health claims for conventional foods will comply with the First Amendment and the court's reasoning in *Pearson*.

Q7. Does the FD&C Act allow FDA to provide safe harbors of approved label text, instead of specific, government-mandated text? Has FDA considered the benefits of such an approach in terms of establishing a system of model claims that would guide industry and consumers and help conserve FDA resources? If not, please explain why not.

Q8. Please provide a summary of FDA's enforcement activities against illegal health claims for each fiscal year from 1996 to the present, including the number of claims FDA reviewed and the number of enforcement actions FDA took by type, e.g., issuing a warning letter or initiating judicial action. Please also provide the number of full-time equivalent personnel assigned to such enforcement during each fiscal year from 1996 to the present.

Q9. Has any FDA official responsible for approving health claims had any contact or correspondence with any government scientists or other government personnel (including advisory committee scientists) outside of FDA who have objected to or commented negatively on any of the health claims at issue in *Pearson*? If so, please provide the name, title, and office of the official; dates of each contact or correspondence; and an explanation of the circumstances surrounding each contact or correspondence.

Q10. The *Pearson* court found that FDA's failure to give any definitional content to the "significant scientific agreement" standard used to evaluate proposed health claims violated the Administrative Procedure Act (5 U.S.C. § 500 *et seq.*) (APA) (*Pearson* at 334). In the evaluation of the health claims at issue in *Pearson*, did FDA comply with all other aspects of APA, the Government in the Sunshine Act (5 U.S.C. § 552b), and the Federal Advisory Committee Act (5 U.S.C. § App. 2)? If not, please explain.

Q11. Did FDA restrict public access under the APA to any documents in connection with the evaluation of the health claims at issue in *Pearson*? If so, please provide copies of those documents and explain why access was restricted. If FDA wishes to withhold access from Congress, please provide a description of each withheld document, including its date.